

**Interagency Coordinating Committee on the Validation of
Alternative Methods (ICCVAM)**

**Expert Panel Evaluation of the Current Validation Status of *In Vitro* Test Methods
for Identifying Ocular Corrosives and Severe Irritants**

Tentative Agenda

Meeting Venue: NIH Campus, Natcher Center
Bethesda, MD

Date: January 11-12, 2005

Objectives for the Expert Panel:

The Panel is charged with developing conclusions and recommendations regarding the current validation status and proposed protocols, validation studies, and reference chemicals for further evaluation of four *in vitro* test methods for identifying ocular corrosives and severe irritants in a tiered testing strategy for regulatory hazard classification and labeling purposes. The Panel is asked to evaluate the information in the appropriate Background Review Document (BRD) to determine the extent that each of the applicable criteria for validation and acceptance of toxicological test methods (ICCVAM 1997, 2003) have been addressed, or will be addressed in proposed studies.

**ICCVAM Ocular Expert Panel Public Meeting
NIH Campus, Natcher Conference Center
Bethesda, MD
Conference Room E1/E2**

Tuesday, January 11, 2005

8:30 a.m. Opening Session (60 min)

1. Call to Order and Panel Introductions (10 min)
(Panel Chair, Dr. Robert Scala)
2. Welcome and Overview of the ICCVAM Test Method Evaluation Process and Charge to the Panel (20 min)
(Dr. William Stokes)
3. Overview of Current Ocular Toxicity Regulatory Testing Procedures and Ocular Hazard Regulatory Testing Requirements and Classification Schemes, (30 min)
(Debbie McCall, EPA)

9:30 a.m. ICE Test Method Evaluation (2 hrs, 40 min) (Primary Reviewers: Robert Scala, Roger Beuerman, June Bradlaw, Wallace Hayes, Robert Peiffer, Nancy Flournoy)

Overview of the ICE Test Method Procedure (15 min)
(Dr. Menk Prinsen)

ICE Test Method: BRD Summary (15 min)
(Dr. David Allen, ILS, Inc./NICEATM)

Proposed Panel Recommendations for the ICE Test Method (30 min)
(Dr. Robert Scala)

10:30 a.m. Break (15 min)

10:45 a.m. Public Comment (20 min)

11:05 a.m. ICE Test Method Evaluation (Continued)

**PANEL DISCUSSION/FINALIZATION OF ICE RECOMMENDATIONS
(100 min)**

12:45 p.m. Lunch (60 min)

1:45 p.m. HET-CAM Test Method Evaluation (2 hrs, 40 min) (Primary Reviewers: Shayne Gad, Donald Fox, Martin Stephens, Frederick Guerriero, Sidney Green, Philippe Vanparys, Nancy Flournoy)

Overview of the HET-CAM Test Method Procedure (15 min)
(Dr. Klaus Krauser)

HET-CAM Test Method: BRD Summary (15 min)
(Dr. Neepta Choksi, ILS, Inc./NICEATM)

Proposed Panel Recommendations for the HET-CAM Test Method (30 min)
(Dr. Shayne Gad)

2:45 p.m. Public Comment (20 min)

3:05 p.m. Break (15 min)

3:20 p.m. HET-CAM Test Method Evaluation (Continued)

**PANEL DISCUSSION/FINALIZATION OF HET-CAM RECOMMENDATIONS
(100 min)**

5:00 p.m. Adjourn for the day

Wednesday, January 12, 2005

8:30 a.m. IRE Test Method Evaluation (2 hr, 40 min) (Primary Reviewers: James Freeman, Sally Atherton, Peter Theran, Yasuo Ohno, Horst Spielmann, David Lovell)

Overview of the IRE Test Method Procedure (15 min)
(Dr. Robert Guest)

IRE Test Method: BRD Summary (15 min)
(Dr. David Allen, ILS, Inc./NICEATM)

Proposed Recommendations for the IRE Test Method (30 min)
(Dr. James Freeman)

9:30 a.m. Public Comment (20 min)

9:50 a.m. Break (15 min)

10:05 a.m. IRE Test Method Evaluation (Continued)

PANEL DISCUSSION/FINALIZATION OF IRE RECOMMENDATIONS
(100 min)

11:45 p.m. Lunch (60 min)

12:45 p.m. BCOP Test Method Evaluation (2 hr, 40 min) (Primary Reviewers: Kathy Stitzel, Henry Edelhauser, Ih Chu, Hiroshi Itagaki, Lionel Rubin, Scheffer Tseng, David Lovell)

Overview of the BCOP Test Method Procedure (15 min)
(Dr. John Harbell)

BCOP Test Method: BRD Summary (15 min)
(Dr. Neepa Choksi, ILS, Inc./NICEATM)

Proposed Recommendations for the BCOP Test Method (30 min)
(Dr. Kathy Stitzel)

1:45 p.m. Public Comment (20 min)

2:05 p.m. Break (15 min)

2:20 p.m. BCOP Test Method Evaluation (Continued)

PANEL DISCUSSION/FINALIZATION OF BCOP RECOMMENDATIONS
(100 min)

4:00 p.m. Reference Substances for Validation Studies (1 hr, 10 min) (Primary Reviewers: Ih Chu, Sidney Green, Yasuo Ohno, Robert Peiffer)

Proposed Reference Substances: BRD Summary (10 min)
(Dr. David Allen, ILS, Inc./NICEATM)

Proposed Reference Substances for the ICE, HET-CAM, IRE, and BCOP Test Methods (15 min)
(Dr. Robert Scala)

4:25 p.m. Public Comment (15 min)

4:40 p.m. Reference Substances for Validation Studies (Continued)

PANEL DISCUSSION/FINALIZATION OF RECOMMENDATIONS ON
REFERENCE SUBSTANCES (45 min)

5:25 p.m. Closing Comments

5:30 p.m. Adjourn